UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/286,189	08/05/1994	SONIA E. SANHUEZA	MISMS1038348	6720

7590 10/01/2004

SIM AND MCBURNEY
330 UNIVERSITY AVENUE
SUITE 701
TORONTO, M5G 1R7
CANADA

EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	40

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/286,189	Applicant(s) SANHUEZA ET AL.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

The final rejection of claims 1, 3-9, and 11-16 was appealed to the Board of Patent Appeals and Interferences. A decision reversing the rejection was rendered by the Board on 27 May, 2004. The Board concluded that "the examiner has overstated his case and/or misapprehended the teachings of the references relied upon" (page 5 of the decision). The examiner does not concur with this assessment. It appears that the Board failed to adequately consider the state-of-the-art vis-à-vis RSV vaccine development. The references as a whole clearly suggest that RSV vaccine development suffers from several limitations and remains an unpredictable undertaking. This is not surprising considering that the correlates of human protection remain to be elucidated. While the cotton rat model is a useful first step for evaluating potential vaccines, nevertheless, the science has not progressed to the point where the skilled artisan can make direct extrapolations between said model and human immune responses. The references relied upon clearly disclose a number of caveats that directly address this point. Apparently the Board failed to appreciate these findings and concluded that the cotton rat model is "of value in this field" (page 6 of the decision). While the model is a useful first step, at this point in time, it is not reasonably predictive of human immune responses. Moreover the model fails to directly address many of the concerns raised in the rejection. As Hall (1994) concluded, "Currently there is no accurate way to predict the response of infants to a candidate vaccine before actual administration" (page 1394, middle column).

The Board also concluded that the examiner did not apply the proper legal standard for enablement. The examiner does not concur with this assessment either. The legal basis for the rejection was

clearly set forth during the prosecution history. See *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988) and *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986) which were cited throughout the prosecution history. The Board appears to rely upon a single decision directed toward different subject matter in making this determination. See *In re Brana*, 51 F.3d 1560, 1568, 34 U.S.P.Q.2d 1436, 1442 (Fed. Cir. 1995). A more relevant decision appears to be *Ex parte Balzarini*, 21 U.S.P.Q.2d 1892 (PTO Bd. Pat. App. Int., 1991). This decision dealt specifically with antiviral agents as opposed to antineoplastic agents. The courts decided that in the absence of suitable experimental evidence from a standard animal model (i.e., one which is reasonably predictive of clinical efficacy), additional data or evidence may be required. The references relied upon by the examiner would clearly lead the skilled artisan to question the predictability of the cotton rat model as it pertains to human vaccine development.

The Board also noted that there may be some unresolved issues that have not been adequately addressed by either party during prosecution. First, the Board concluded that there may be some issues pertaining to the method of making the vaccine composition that need to be addressed under 35 U.S.C. § 112, first paragraph. Second, the Board concluded that similar issues may be present in related U.S. Application No. 08/583,124, which may necessitate the filing of a terminal disclaimer or other appropriate action. Accordingly, prosecution with respect to claims 1, 3-9, and 11-16 is hereby reopened.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-9, 15, and 16, are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As previously set forth, the claimed invention is directed toward a non-immunopotentiating inactivated RSV vaccine composition and attendant methods of use. The crux of the invention appears to be the discovery that the removal of cellular and serum components, as well as, a specific method of inactivating the virus (i.e., using β-propiolactone, one of two specific non-ionic detergents, or ascorbic acid) produce an inactivated RSV vaccine with reduced immunopotentiative properties. In rendering their decision, the Board stated that "Appellants acknowledge that the prior art establishes that formalin inactivated RSV vaccines did not work." The disclosure describes four specific inactivating agents that appear to be enabled. The disclosure does not disclose any other agents. Appropriate amendment of the claim language to include these four specific embodiments would be acceptable.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those

in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide adequate guidance pertaining to other inactivating agents that can reasonably be expected to produce an inactivated RSV vaccine with the desired characteristics.

2) The disclosure fails to provide a sufficient number of working embodiments that would enable the full breadth of the patent protection desired.

3) The state-of-the-art vis-à-vis RSV vaccine development is one of unpredictability.

Therefore, when all the aforementioned factors are considered it would clearly require undue experimentation to practice the claimed invention.

Non-statutory Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); and *In re Goodman*, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting

application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 5-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, and 14-16 of allowed U.S. Application No. 08/583,124. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *In re Berg*, 140 F.3d 1428, 46 U.S.P.Q.2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application are anticipated by the claims of the '124 application. Applicants may obviate the rejection by filing a terminal disclaimer or canceling the claims.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington,

VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

24 September, 2004